RD2008-13

Registration Decision

Pyraclostrobin

Insignia EG Fungicide
Headline EC Fungicide
Cabrio EG Fungicide

(publié aussi en français)

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

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Registration Decision for Pyraclostrobin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Insignia EG Fungicide and is granting the conversions from conditional to full registration for Pyraclostrobin Technical Fungicide, Headline EC Fungicide and Cabrio EG Fungicide. The above mentioned end-use products contain the technical grade active ingredient pyraclostrobin to control a variety of fungal diseases on agricultural crops or on golf course turf.

An evaluation of available scientific information determined that, under the proposed conditions of use, these products have value and do not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2008-04, *Pyraclostrobin, Insignia EG Fungicide, Headline EC Fungicide, Cabrio EG Fungicide*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for pyraclostrobin and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in Proposed Registration Decision, *Pyraclostrobin, Insignia EG Fungicide, Headline EC Fungicide, Cabrio EG Fungicide* (PRD2008-04).

For more details on the information presented in this Registration Decision, please refer to the PRD2008-04, Proposed Registration Decision, *Pyraclostrobin, Insignia EG Fungicide, Headline EC Fungicide, Cabrio EG Fungicide*, that contains a detailed evaluation of the information submitted in support of this registration.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration.[3] The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk-assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What Is Pyraclostrobin?

Pyraclostrobin is the active ingredient in Headline EC Fungicide, Cabrio EG Fungicide and Insignia EG Fungicide. It is a fungicide applied to the foliage that is used to control a variety of fungal pathogens on plants. It has a protective effect by inhibiting spore germination and also a curative effect by inhibiting mycelial growth.

Headline EC Fungicide and Cabrio EG Fungicide control fungal pathogens in agricultural crops as well as certain grasses. Insignia EG Fungicide controls numerous fungal diseases on golf course turf.

Health Considerations

Can Approved Uses of Pyraclostrobin Affect Human Health?

Pyraclostrobin is unlikely to affect your health when used according to label directions.

Exposure to pyraclostrobin may occur through diet (food and water), when handling and applying the product or when working in treated areas. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels

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[3] "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

[4] "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using pyraclostrobin products according to label directions.

Pyraclostrobin did not cause cancer in animals and was not genotoxic. There was also no indication that pyraclostrobin caused damage to the nervous system and there were no effects on reproduction. The first signs of toxicity in animals given daily doses of pyraclostrobin over long periods of time were effects on the gastrointestinal tract, liver and spleen. The risk-assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When pyraclostrobin was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, though the effects observed were more severe, indicating that the fetus was more sensitive to pyraclostrobin than the adult animal. Consequently, extra protective measures were applied during the risk assessment to further reduce the allowable level of human exposure to pyraclostrobin.

Residues in Water and Food

Dietary risks from residues in food and water resulting from the use of Headline EC Fungicide and Cabrio EG Fungicide are not of concern.

Aggregate dietary intake estimates (food and water) revealed that the general population and children 1 to 2 years old, the subpopulation which would ingest the most pyraclostrobin relative to body weight, are expected to be exposed to less than 31.6% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from pyraclostrobin is not of concern for all population subgroups.

Animal studies revealed acute health effects. The acute aggregate (food and water) dietary intake estimate for females 13 to 49 years of age used less than 92.8% of the acute reference dose, which is not a health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using pyraclostrobin on banana, berries, bulb vegetables, cereal grains, citrus fruits, cucurbit vegetables, fruiting vegetables, grapes, succulent or dried legume vegetables, peanut, root and tuber vegetables, stone fruits, strawberries and tree nuts were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of PRD2008-04.

Occupational Risks From Handling Pyraclostrobin

Occupational risks are not of concern when Insignia EG Fungicide, Headline EC Fungicide and Cabrio EG Fungicide are used according to label directions, which include protective measures.

For bystanders, exposure is expected to be much less than that of field workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Insignia EG Fungicide

The label will specify that anyone mixing, loading or applying Insignia EG Fungicide or involved in clean-up or repair activities must wear a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves, and that Insignia EG Fungicide is for application to golf course turf only. When using low-pressure turf gun application equipment, mixers/loaders and applicators must also wear respiratory protection. Taking these label requirements into consideration, risk to workers handling Insignia EG Fungicide is not a concern.

Headline EC Fungicide and Cabrio EG Fungicide

As a result of the evaluation of new data, the dermal and inhalation exposure and risk estimates for all uses currently on the labels for Cabrio EG Fungicide and Headline EC Fungicide were reassessed. The personal protective measures on the labels were updated accordingly. Taking the label requirements into consideration, risk to workers handling or exposed to areas freshly treated with Headline EC Fungicide or Cabrio EG Fungicide is not of concern.

Environmental Considerations

What Happens When Pyraclostrobin Is Introduced Into the Environment?

Pyraclostrobin is a risk to aquatic organisms; therefore, buffer zones are required to mitigate this risk during application.

Pyraclostrobin enters the environment when used as a fungicide on turf and agricultural crops. Based on its low volatility, pyraclostrobin residues are not expected in the air. Pyraclostrobin is persistent in aerobic soil and non-persistent in anaerobic soil. Neither hydrolysis or phototransformation is an important route of transformation for pyraclostrobin in terrestrial environments. Pyraclostrobin and its major transformation

products are immobile in sediment; hence, leaching is not an important route of dissipation. Pyraclostrobin is not persistent in the aquatic environment. Phototransformation is an important route of transformation for pyraclostrobin in the aquatic environment and most major transformation products are transient. Hydrolysis of pyraclostrobin is not an important route of transformation in the aquatic environment.

Pyraclostrobin poses a very high risk to aquatic invertebrates, plants and fish. It also poses a high dietary risk and a moderate reproduction risk to small mammals.

Value Considerations

What Is the Value of Insignia EG Fungicide, Headline EC Fungicide and Cabrio EG Fungicide?

Insignia EG Fungicide

Used according to the label and with appropriate resistance management techniques, Insignia EG Fungicide provides effective control of a wide range of turfgrass diseases, including brown patch, gray leaf spot, gray snow mould/typhula blight, leaf spot, pink snow mould, pythium blight and rust.

There are many fungicides registered for control of turf diseases, including two others with a similar active ingredient, e.g. strobilurins. The addition of pyraclostrobin provides yet another strobilurins for turf disease management.

Headline EC Fungicide and Cabrio EG Fungicide

Headline EC Fungicide and Cabrio EG Fungicide are broad spectrum foliar fungicides registered for use a wide variety of agricultural crops. Both end-use products fit well into integrated pest management strategies due to their strong activity on multiple diseases and their low risk to beneficial insects and arthropods. They can also be replacements for older fungicides through substitution of applications or elimination of sprays due to the longer residual effect of pyraclostrobin.

A value assessment of Headline EC Fungicide and Cabrio EG Fungicide was presented in Regulatory Note REG2003-06, *Pyraclostrobin, Headline EC, Cabrio EG*. To support aerial application for both of these products, confirmatory efficacy data were required on chickpeas and potatoes for Headline EC and on one stonefruit crop for Cabrio EG.

A comparison of aerial applications to ground applications was reviewed for Headline EC Fungicide. Three trials were on leaf spot diseases on wheat, four trials were on potato early blight and two trials were on ascochyta blight of chickpeas. None of these trials demonstrated an appreciable difference in efficacy between the two application methods. Therefore, aerial application of Headline EC Fungicide is fully supported for all crops on

the label with the exception of sugar beets. As the upper rate range for sugar beets is higher than the rest of the label (0.9 L/ha vs 0.67 L/ha), buffer zones will be affected if applied by air. Therefore sugar beets will not be supported for aerial application at this time.

For Cabrio EG Fungicide, aerial trials were submitted on cucumbers and melons, but not on stonefruits. In addition, the product tested in these trials was not Cabrio EG Fungicide, but a different formulation of pyraclostrobin. The request for aerial application on the Cabrio EG Fungicide label was subsequently withdrawn.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures proposed on the labels of Insignia EG Fungicide, Headline EC Fungicide and Cabrio EG Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

- **Human Health**

For Insignia EG Fungicide

- Persons mixing, loading or applying Insignia EG Fungicide or performing clean-up or repair activities must wear a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves.

- When using low pressure turf gu.. application equipment, mixers/loaders and applicators must also wear respiratory protection.

For Headline EC Fungicide, the label must be amended as follows

- Persons mixing/loading or involved in clean-up and repair activities with Headline EC Fungicide must wear goggles or face shield and coveralls over a long-sleeved shirt and long pants, socks and footwear. Anyone applying Headline EC Fungicide must wear a long-sleeved shirt, long pants, gloves, socks and footwear. Gloves are not required for an applicator in an enclosed cab. Commercial applicators must use groundboom equipment with an enclosed cab.

- Do not enter or allow workers entry into the areas treated with Headline EC Fungicide during the restricted-entry interval (REI) of 12 hours, except in the case of corn, which the REI is 7 days for hand harvesting or detasseling activities.

For Cabrio EG Fungicide, the label must be amended as follows

- Anyone mixing/loading, applying or involved in clean-up or repair activities with Cabrio EG Fungicide must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and footwear. For mixing/loading and applying to more than 100 ha of root vegetables, a closed mixing, loading and application system must be used.

- Do not enter or allow workers entry into treated areas for the following REIs specified for each crop:

Lowbush berries, fruiting vegetables and strawberries:	12 hours for all activities
Highbush berries:	28 days for hand harvesting and 12 hours for all other activities
Bulb vegetables:	3 days for thinning and 12 hours for all other activities
Cucurbit vegetables:	3 days for hand harvesting, thinning and pruning and 12 hours for all other activities
Root vegetables:	3 days for hand harvesting and 12 hours for all other activities
Stone fruits:	9 days for hand thinning and pruning and 12 hours for all other activities

- **Environment**

For Insignia EG Fungicide

To protect sensitive aquatic and terrestrial habitats from the use of pyraclostrobin, mitigative measures are recommended. These include adding precautionary statements to the label regarding environmental hazards and the directions for use, as well as buffer zones to protect sensitive aquatic and terrestrial habitats from spray drift. Therefore, buffer zones of 1 to 20 metres for ground application are required to protect nearby freshwater, estuarine/marine and terrestrial habitats from the effects of spray drift.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Appendix I Comments and Responses

1.0 Comments On the Guarantee For the End-use Product Insignia EG Fungicide

A comment was received that the guarantee for Insignia EG Fungicide, on page 9 of PRD2008-04, should read 19.4% to 20.6 % instead of the mentioned 20.6 to 20.6 %.

Response

PMRA is in agreement that the limits for the guarantee of the end-use product Insignia EG Fungicide should read 19.4% to 20.6%.

2.0 Comments On the Toxicology Endpoints (Page 14 of PRD2008-04)

A comment was received that a threefold factor has been retained in PRD2008-04 to address the sensitivity to the young observed in the rabbit developmental study. Therefore, the target MOE is reported as 300.

The comment indicated that the developmental toxicity study data adequately determines a no observed adverse effect level (NOAEL) and this provides sufficient health protection for all groups when used with intraspecies and interspecies factors of 10 × 10. Introduction of an additional 3× safety factor leads to unnecessarily conservative compounding effects because the 100× factor is applied to the NOAEL reflecting the sensitivity of the young in the developmental study and there are no data deficiencies that would warrant applying a *Pest Control Products Act* factor. Similarly, in the application of a 300× rather than a 100× factor to the repeat-dose inhalation study, the NOAEL for the rabbit developmental study trigger is effectively > 20× higher than the inhalation study NOAEL, so 100× would provide more than adequate protection, and avoids double-counting.

Response

Toxicological Risk Assessment

The appropriateness of the applied composite assessment factor was reassessed based on recent developments in PMRA policy. The factor was found to have been applied appropriately to the occupational and dietary endpoints established on the NOAEL from the developmental toxicity study in rabbits, to address concerns regarding prenatal toxicity. In the intermittent short- to intermediate-term inhalation exposure scenarios, a NOAEL from a short-term inhalation study was used with an MOE of 100-fold, which results in a 2100-fold margin to the NOAEL in the rabbit developmental toxicity study. Therefore no additional uncertainty factor was required.

Effects of the toxicological risk assessment on Insignia EG Fungicide, Headline EC Fungicide and Cabrio EG Fungicide

For Insignia EG Fungicide, the revisions of the toxicological risk assessment do not affect the occupational risk assessment or the required label amendments.

For Headline EC Fungicide and Cabrio EG Fungicide, only mixer/loader/applicator inhalation exposure and risk estimates were updated. The updated exposure and risk estimates are presented in Table 1 and 2 below. As the target MOE for dermal exposure and risk estimates is still 300, the dermal exposure and risk estimates for mixer/loader/applicator and postapplication workers were not revisited.

The precautionary statements related to occupational exposure on the pending labels were modified to remove the requirement of wearing a respirator while mixing/loading for various crops.

Table 1 Mixer/Loader/Applicator Inhalation Exposure and Risk to Headline EC

Crop	Occupational Scenario	Inhalation Exposure[1] (mg/kg bw/day)	Margin of Exposure (based on a NOAEL of 0.23 mg/kg bw/day[2])
Wheat,[3] lentil,[4] succulent shelled beans and peas	Mixer/loader + groundboom application (farmer)	0.0008	280
	Mixer/loader + groundboom application (custom)	0.0011	216
	Mixer/loader (for aerial application)	0.0017	137
	Aerial application	0.0001	3129
Corn	Mixer/loader + groundboom application (farmer)	0.0008	280
	Mixer/loader + groundboom application (custom)	0.0011	216
Potato[5]	Mixer/loader + groundboom application (farmer)	0.0005	468
	Mixer/loader + groundboom application (custom)	0.0012	192
Sugar Beet	Mixer/loader + groundboom application (farmer)	0.0007	349
Grass grown for seed	Mixer/loader + groundboom application (farmer)	0.0009	250
	Mixer/loader + groundboom application (custom)	0.0012	192
	Mixer/loader (for aerial application)	0.0019	122
	Aerial application	0.0001	2794
Alfalfa for seed	Mixer/loader + groundboom application (farmer)	0.0005	419
	Mixer/loader + groundboom application (custom)	0.0007	323
	Mixer/loader (for aerial application)	0.0011	205
	Aerial application	0.00005	4600

1 Based on a open mixing and loading system with mixer/loaders wearing a single layer and gloves, groundboom and aerial applicators wearing a single layer and no gloves. For custom groundboom application, a closed cab scenario was used; for all other groundboom application scenarios (i.e. farmer), an open cab scenario was used.
Daily dose = default area treated (ha/day) × application rate (kg a.i./ha) × PHED exposure (µg a.i./kg) × conversion factor (1 mg a.i./1000 µg a.i./kg)/(70 kg bw).

2 Based on the 28-day inhalation study, target MOE = 100.

3 Wheat is the representative crop for wheat, barley, rye and chickpeas.

4 Lentil is the representative crop for legume vegetables including edible-podded legume vegetables, dry and succulent peas, dry and succulent beans and soybeans.

5 At a lower application rate of 0.168 g a.i./ha.

Table 2 Mixer/Loader/Applicator Inhalation Exposure to Cabrio EG Fungicide

Crop	Occupational Scenario	Exposure[1] (mg/kg bw/day)		Margin of Exposure (based on a NOAEL of 0.23mg/kg bw/day)[2]
Bulb Vegetables (onion)[3] and Cucurbit Vegetables (cucumber, cantaloupe, squash)[4]	Mixer/loader + groundboom application	Farmer	0.0002	1513
Fruiting Vegetables (field peppers and field tomatoes)[5]	Mixer/loader + groundboom application	Farmer	0.0002	1271
Root Vegetables (carrot)[6]	Mixer/loader + groundboom application	Farmer	0.0005	454
Highbush blueberries	Mixer/loader + airblast application	Farmer	0.0002	984
Lowbush blueberries	mixer/loader + groundboom application	Farmer	0.0001	3388
Strawberries	Mixer/loader + groundboom application	Farmer	0.00002	10164
Grapes	Mixer/loader + airblast application	Farmer	0.0002	1004
Stone Fruits (peach)[7]	Mixer/loader + airblast application	Farmer	0.0004	587
Stone Fruits (cherries)[8]	Mixer/loader + airblast application	Farmer	0.0001	2936

1 Based on individuals wearing a single layer of clothing and gloves except for the groundboom applicators not wearing gloves. Daily dose = default area treated (ha/day) × application rate (kg a.i./ha) × PHED exposure (µg a.i./kg) × conversion factor (1 mg a.i./1000 µg a.i./kg)/body weight (70 kg)

2 Based on the 28-day inhalation study, target MOE = 100

3 Green onions are the representative crop for bulb vegetables

4 Field cucumbers are the representative crop for cucurbit vegetables

5 Field tomatoes are the representative crop for Fruiting vegetables

6 Carrots are the representative crop for root vegetables

7 Peaches are the representative crop for stone fruits

8 Closed mixing/loading and application

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

1.0 Impact on Human and Animal Health

Toxicology:

PMRA 1087938 2005, BAS 500 F- Subacute Inhalation Study in Wistar Rats: 20 Aerosol Exposures During 4 Weeks Experimental Toxicology and Ecology,, 4010494/96073, DACO: 4.3.6

PMRA 951588 2001, Pyraclostrobin (BAS 500 F): Historical Control Tumor Data, DACO: 4.8

PMRA 951589 2001, Pyraclostrobin (BAS 500 F): Historical Control Tumor Data - Second Submission - Leydig Cell Tumors and Adrenal Cortical Tumors, DACO: 4.8

PMRA 951590 2000, Amended Report: Pyraclostrobin (BAS 500 F): Historical Control Data on Non- Neoplastic Lesions in Chronic Rat Studies, DACO: 4.8

PMRA 951687 2002, Summary Points from BASF Responses to Pyraclostrobin Joint Review, DACO: 4.8

PMRA 951688 2002, Chronic and Oncogenicity Studies with BAS 500 F (Pyraclostrobin): Further Evaluations of Body Weight, Food Consumption and Food Efficiency, DACO: 4.8

Food Residue Assessment:

PMRA 1088016 2005, Independent Laboratory Validation (ILV) of the SOP-PA.0265 for the Determination of BAS 500 F and Its Metabolite BF 500-16 Residues in Animal Tissue - Hen (Heart/Muscle), Report No. BASF Study Code - IPMIS 183901; LAARL RESVAL 847-05, MRID: N/S, DA

PMRA 1088017 2000, Investigation of the Stability of BAS 500 F (Reg. No. 304428) in Sample Materials of Animal Origin Under Usual Storage Conditions, Report No. 35913, MRID: N/S, DACO: 7.3

PMRA 1088018 2005, The Magnitude of Pyraclostrobin Residues in Dry Peas and Lentils (2004 Supplemental Data for US and Canada), NC Report No. 172171, MRID: N/S, DACO: 7.4.1

PMRA 1088019 2001, Freezer Storage Stability of BAS 500 F and BF 500-3 in Plant Matrices Including Processed Commodities, Report No. 66414, MRID: N/S, DACO: 7.4.3

PMRA 1088020 2005, Memorandum from USEPA dated May 5, 2005 regarding Pyraclostrobin - Storage Dates for Confined Rotational Crop Study, N/S, MRID: N/S, DACO: 7.4.3

PMRA 1088272 2005, Magnitude of BAS 510 F and BAS 500 F Residues in Bulb Vegetables After Application of BAS 516 04 F, Report No. BASF Study No. 190537, MRID: N/S, DACO: 7.4.1

PMRA 1088273 2005, The Magnitude of BAS 510 F and BAS 500 F Residues in Cucurbits, Report No. BASF Study No. 190531, MRID: N/S, DACO: 7.4.1

PMRA 1088274 2005, The Magnitude of BAS 510 F and BAS 500 F Residues in Stone Fruit, Report No. BASF Study No. 190555, MRID: N/S, DACO: 7.4.1

PMRA 1088275 2005, The Magnitude of BAS 510 F and BAS 500 F Residues in Berries, Report No. BASF Study No. 190549, MRID: N/S, DACO: 7.4.1

Occupational Exposure:

PMRA 1125878 2000, BAS 500 F Turf Transferable Study in Turf., 97235, MRID: 45118725, DACO: 5.9

PMRA 1125879 1998, Validation of BASF Analytical Method D9803 for the analysis of BAS 500F on cloth matriez for use in the determination of turf transferable residue., 98039 980021, MRID: 45118730, DACO: 5.9

PMRA 1125882 2001, Response to questions from PMRA deficiency review Level C for : BAS 500 F disclodeable Foliar Resi\due Study in Turf., DACO: 5.9

PMRA 1125883 2000, BAS 500 00F and BAS 500 01F: Tank mix uniformity of BAS 500 00F and BAS 500 01F in Simulated spray Tank mixtures, 60174, DACO: 5.9

PMRA 742196 2003, 14C-BAS 500 F - Study of the Dermal Absorption in Rats, Report No. 01B0118/036003, MRID: N/S, DACO: 5.8

2.0 Impact on the Environment

PMRA 1087933 Effects of BAS 500 00 F on seedling emergence and growth of selected non-target terrestrial plants (Tier 1). Laboratory Study No. 46887. Study report date: 18-October-2001. BASF Registration Document No. 2001/5002405. 51 pages. DACO 9.8.4.

PMRA 1087934 Effects of BAS 500 00 F on vegetative vigor of selected non-target terrestrial plants (Tier 1). Laboratory Study No. 46888. Study report date: 18-October-2001. BASF Registration Document No. 2001/5002406. 49 pages. DACO 9.8.4.

PMRA 1359262 Acute toxicity of Reg No. 340266 (metabolite of BAS 500F) to *Daphnia magna* Straus in a 48 hour static test. BASF Study Code 172480. Study report date: 21-December-2006. BASF Registration Document No. 2006/1038907. 20 pages. DACO 9.3.2.

PMRA 1359263 Effect of BF 500-3 (Reg. No. 340266, metabolite of BAS 500F) on the growth of the green alga *Pseudokirchneriella subcapitata*. BASF Study Code 172483. Study report date: 22-December-2006. BASF Registration Document No. 2006/1038445. 31 pages. DACO 9.8.2.

PMRA 1370731 Reg. No. 340266 (metabolite BF 500-3 of BAS 500F): acute toxicity study on the rainbow trout (*Oncorhynchus mykiss*) in a static system over 96 hours. Experimental Toxicology and Ecology. Laboratory Project No. 12F0681/065050. 06-February-2007. BASF Registration Document No. 2007/1010836. 41 pages. DACO 9.5.2.1.

PMRA 1269077 Re: Pyraclostrobin technical fungicide, containing pyraclostrobin Reg. No. 27321 TGAI, Submission Number 2005-3432. 2 pages.

3.0 Value

PMRA 1088015 2005, Submission of Aerial Data to Support Condition of Registration, N/S, MRID: N/S, DACO: 10.2.3.3

PMRA 959218 2000, Insignia Pyraclostrobin (Proposed): TURF SUMMARY, N/S, MRID: N/S, DACO: 10.1

PMRA 959219 2000, Insignia Pyraclostrobin (Proposed): Petition for Application in Turf, DACO: 10.1,10.2,10.2.2,10.2.3.1,10.2.3.3,10.3.1,10.3.2

PMRA 959220 2000, Turf: Trial Abstracts, N/S, MRID: N/S, DACO: 10.2.3.3,10.3.2

PMRA 959221 2001, Response to Questions from PMRA Deficiency review Level C: BAS 500F Value- Turf, N/S, MRID: N/S, DACO: 10.2.3.3

PMRA 959419 2000, Turf: Trial Abstracts, N/S, MRID: N/S, DACO: 10.2.3.3,10.3.2

B. ADDITIONAL INFORMATION CONSIDERED

Published Information

Pest Management Regulatory Agency, 2003. Regulatory Note REG2003-06, *Pyraclostrobin, Headline EC, Cabrio EG.* pp. 106.